

REMARKS

Claims 1-16 have been rejected. No claims have been allowed. Claims 1-16 are pending in the application.

Claim 1 has been amended to claim improvements in the sampling and analysis member 15 which is used to assay for an analyte of interest in a sample. Claim 1 has been amended further to include the polymeric material limitations of non-fibrous material which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. The support for the sampling swab used in a sampling and analysis member is found in paragraph 56 of the specification. The support for the reagent disc used in a sampling and analysis member is found in paragraph 65 of the specification. The support for non-fibrous material is found in paragraph 67 of the specification. The support for the absorptive capacity and pore size of the material is found in original Claim 2 and paragraph 25 of the specification. All other claims depend upon Claim 1 and therefore, incorporate these limitations.

The present invention is a sampling and analysis member (such as member 15) which is used to assay for an analyte of interest in a sample which includes a non-

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fibrous polymeric material as a sampling swab and reagent disc which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. The polymeric material is advantageous in that it is durable, resistant to chemical attack by fluids of either high or low pH, non-fibrous, absorbant, and resistant to shredding and crumbling at the edges (paragraph 0070, pages 32-33 in the specification).

Claim Rejections

1. Claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 6 and 11 of U.S. Patent No. 6,548,018.

Enclosed is a Terminal disclaimer in order to avoid the 35 U.S.C. 102(e)/35 U.S.C. 103 double patenting rejection. It is believed that this overcomes the rejection. Reconsideration of the rejection is requested.

2. Claims 1-5 and 9-16 were rejected under 35 U.S.C. §102(a) as being anticipated by Applicant's admission of prior art.

Claim 1 has been amended to claim improvements of a sampling and analysis member which is used to assay for an analyte of interest in a sample. Claim 1 has been amended further to include the polymeric material limitations of non-fibrous material which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. Claims 2-5 and 9-16 are all dependent upon Claim 1 and therefore, incorporate these limitations.

Applicant shows at pages 31-32 and 37 in the specification of known, commercially available materials which meet the characteristics of the porous, non-fibrous absorbent polymeric material, such as Merocel® CF200 and Merocel® CF50. The prior art does not show or suggest a sampling and analysis member which is used to assay for an analyte of interest in a sample having a medium comprising the porous, non-fibrous absorbent polymeric material.

According to M.P.E.P. §2131 a claim is anticipated only if each and every element as set forth in

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the claim is found, either expressly or inherently described, in a single prior art reference. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The prior art does not show or suggest a sampling and analysis member which is used to assay for an analyte of interest in a sample with a medium comprising the claimed porous, non-fibrous absorbent polymeric material. Therefore, the Claims are not anticipated by the prior art. In light of these amendments, the Claims are patentable over the prior art materials. Reconsideration of the rejection is requested.

3. Claims 6-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Applicant's admission of prior art.

Claim 1 has been amended to claim improvements of a sampling and analysis member which is used to assay for an analyte of interest in a sample. Claim 1 has been amended further to include the polymeric material

limitations of non-fibrous material which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. Claims 6-8 are dependent upon Claim 1 and therefore incorporate these limitations.

As noted previously, Applicant shows at pages 31-32 and 37 in the specification of known, commercially available materials which meet the characteristics of the porous, non-fibrous absorbent polymeric material, such as Merocel® CF200 and Merocel® CF50. According to MPEP §2143.03, all claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). The prior art does not show or suggest a sampling and analysis member which is used to assay for an analyte of interest in a sample having a medium comprising

the porous, non-fibrous absorbent polymeric material.

To establish a *prima facie* case of obviousness, three criteria must be met, as found in M.P.E.P. §2143. There must be first some suggestion or motivation to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations. This teaching or suggestion to make the claimed combination must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). There is no teaching or suggestion of all of the claim limitations by the prior art. Additionally, there is no suggestion or motivation to combine these limitations of a polymeric material with a sampling and analysis member which is used to assay for an analyte of interest in a sample outside of the Applicant's disclosure in this case. Therefore, no *prima facie* case of obviousness can be established. In light of these amendments, the Claims are patentable over the prior art materials. Reconsideration of the rejection is requested.

4. Claims 1, 3, 4, 9 and 11-16 were rejected under

35 U.S.C. §102(b) as being anticipated by Rosenblatt (U.S. Patent No. 4,098,728).

Claim 1 has been amended to claim improvements of a sampling and analysis member which is used to assay for an analyte of interest in a sample. Claim 1 has been amended further to include the polymeric material limitations of non-fibrous material which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. Claims 3, 4, 9 and 11-16 are dependent upon Claim 1 and therefore incorporate these limitations.

Rosenblatt teaches a hydrophilic medical sponge comprising polyvinyl alcohol with high fluid holding capacity. Rosenblatt further teaches the use of such material as a diagnostic swab. Rosenblatt does not show or suggest a sampling and analysis member which is used to assay for an analyte of interest in a sample. As cited previously, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since Rosenblatt does not show or suggest a sampling and analysis member which is used to assay for an

analyte of interest in a sample which includes the polymeric material, anticipation of the claimed invention cannot be established. In light of these amendments, the Claims are patentable over Rosenblatt. Reconsideration of the rejection is requested.

5. Claims 2, 5-8 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenblatt (U.S. Patent No. 4,098,728).

Claim 1 has been amended to claim improvements of a sampling and analysis member which is used to assay for an analyte of interest in a sample. Claim 1 has been amended further to include the polymeric material limitations of non-fibrous material which has an absorptive capacity between about 5 g water/g of polymeric material to about 15 g water/g of polymeric material, and a pore size between about 0.004 mm to about 1.2 mm. Claims 2, 5-8 and 10 are dependent upon Claim 1 and therefore incorporate these limitations.

Rosenblatt teaches a hydrophilic medical sponge comprising polyvinyl alcohol with high fluid holding capacity. Rosenblatt further teaches the use of such material as a swab, and that characteristics such as pore

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size can be varied. All claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention, however Rosenblatt does not show or suggest a sampling and analysis member which is used to assay for an analyte of interest in a sample that incorporates such a polymeric material.

The limitations of the presently claimed invention are not taught or suggested by the prior art and there is no motivation to combine the teachings of the prior art of polymeric materials with a sampling and analysis member which is used to assay for an analyte of interest in a sample. Therefore, no *prima facie* case of obviousness can be established. In light of these amendments, the Claims are patentable over Rosenblatt. Reconsideration of the rejection is requested.

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The cited references do not teach all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 1-16 are patentable and in condition suitable for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully,



Ian C. McLeod

Registration No. 20,931

McLEOD & MOYNE, P.C.
2190 Commons Parkway
Okemos, Michigan 48864

(517) 347-4100
Fax: (517) 347-4103

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